REMARKS

The Official Action of 29 November 2007 has been carefully considered and reconsideration of the application as amended is respectfully requested.

Claim 1 has been amended in accordance with the disclosure in the specification as filed at, for example, paragraph [0036] on page 10 to emphasize that the claimed method preferentially disrupts malfunctioning, as opposed to normal, cells. The claims have also been amended to remove the bases for the rejections under 35 USC 112, second paragraph appearing at paragraph 8 of the Official Action. In particular, the relative term "substantial" has been eliminated from the specification and the other terms that the Examiner considered to be indefinite have been qualified with functional limitations as expressly sanctioned by MPEP 2173.05(g). With specific respect to claims 19, 54, 79 and 87, the lower limit of the thickness of the target is defined by the functional limitation of having the capability of providing the line emission X-rays. All claims as amended are respectfully considered to be sufficiently definite to satisfy the dictates of 35 USC 112, second paragraph.

Certain claims stand rejected under the enablement requirement of 35 USC 112, first paragraph, because the claims are not limited to the treatment of a specific type of cancer and the prior art, as represented by the Goldman et al textbook cited on page 7 of the Official Action, allegedly teaches that there is no one specific treatment that is effective for all types of cancer. Applicants respectfully traverse this rejection.

First, Applicant respectfully notes that the cited art reference, Goldman et al, distinguishes between radiation therapy (Goldman et al at pages 1061-2) and medical therapy, including chemotherapy (Goldman et al at pages cited by Examiner). The Examiner has relied upon Goldman et al to show the alleged unpredictability in using **chemotherapy** for treating all types of cancer cells, but has respectfully overlooked the fact that the claims are directed to **radiation therapy**.

Indeed, the claimed invention provides a tool for the **preferential or selective** removal of tumor cells (as opposed to normal or healthy cells) by radiosurgery that is similar, by way of example, to a surgical method for the removal of tumor cells with use of an improved scalpel. Just as claims to a method for selective removal of tumor cells with an improved scalpel would not be considered to be non-enabling simply because it may not be possible to remove all tumor cells in a tumor using the scalpel without also removing healthy cells, a method for preferential destruction of tumor cells by radiosurgery cannot be considered to be non-enabling simply because it may not be possible to destroy all tumor cells in a tumor using the radiosurgery method without also destroying some healthy cells. In each case, those of skill in the art would be able to determine without undue experimentation those tumors, if any, which may not be operable with the selected method (tool). See, also, MPEP 2164.08(b) ("The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled.").

This is especially true in a case where, as here, the state of the art provides a tremendous amount of guidance in the use of radiosurgery as a tool for treating tumors.

This is shown by Cash et al US Patent 6,366,801 (cited at paragraph [0004] of specification; copy submitted herewith). It is also shown by Goldman et al, at pages 1061-1062 ("Compared with surgery, radiation therapy has distinct advantages in the locoregional treatment of cancer. Radiation causes less acute morbidity and can be curative for some specific sites while preserving organ or tissue structure and function."). Thus, Applicant respectfully submits that the state of the art establishes that the application is enabling for the invention as claimed. See MPEP 2164.05(a) ("The state of the prior art provides evidence for the degree of predictability in the art and is related to the amount of direction or guidance needed in the specification as filed to meet the enablement requirement. The state of the prior art is also related to the need for working examples in the specification.").

In any event, the USPTO has respectfully not met its initial burden to establish a reasonable basis to question the enablement provided for the claimed invention in the specification as filed. As stated in MPEP 2164.04, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure."

In the present case, the only reason provided by the Examiner for the rejection is an alleged teaching in Goldman et al that there is no one specific chemotherapeutic agent that is effective to treat all types of cancers. However, as discussed above, the claimed

invention is not directed to a chemotherapeutic agent but to an improved method for radiosurgery. Accordingly, and as discussed above, the provided reason is respectfully **not** applicable to the invention as claimed and the USPTO has respectfully not met its initial burden of establishing even a *prima facie* case of lack of enablement for the claimed invention.

Certain claims also stand rejected under the written description requirement of 35 USC 112, first paragraph, because the specification allegedly does not reasonably convey that Applicant had possession of the invention defined by the claims as of the application filing date (see paragraph 10 of the Official Action). In setting forth this rejection, the Examiner has respectfully overlooked that the subject matter for which the Examiner contends there is a lack of adequate written description is described in the **original claims**. See original claims 1, 20, 22, 30-35, 55, 80, 82, 85, and 98. The original claims are of course part of the disclosure and must be taken into account in determining compliance with the written description requirement of 35 USC 112, first paragraph. See MPEP 2163 (" There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. . . .Consequently, rejection of an original claim for lack of written description should be rare.").

Although there are circumstances (pertaining primarily to the claiming of genetic material) where the issue of an alleged lack of adequate written description may arise even for an original claim, the Examiner has respectfully not met the USPTO's initial burden of setting forth even a *prima facie* case of an alleged lack of adequate written description in this regard. See MPEP 2163.04 (stating that, to establish a *prima facie*

case for an alleged violation of the written description requirement, an Examiner must provide "reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention **as claimed** in view of the disclosure of the application as filed."). In the present case, the claims are commensurate in scope with the disclosure as filed and the only reasons presented by the Examiner to support the rejection pertain to limitations that are **not** claimed and that, in any event, were well known to those of skill in the art as of the application filing date (e.g., the K-absorption or L-absorption edge for platinum). In the absence of even a *prima facie* case for an alleged lack of written description, Applicant respectfully submits that the rejection should be withdrawn.

The claims stand rejected under 35 USC 103(a) as allegedly being unpatentable over Mills in view of Wang. Applicant respectfully traverses this rejection.

The claimed invention is based on Applicant's finding that it is possible preferentially to disrupt cancer cells, by administering to a patient a compound that associates with DNA in the cells and then selectively irradiating a localized region containing the cells with **line emission x-rays** that lead to a massive Auger cascade and cell death. In contrast, the primary reference cited by the Examiner teaches away from radiation therapy with the use of such x-rays. In particular, Mills teaches at column 1, lines 21-49 that the therapy described therein is an alternative to radiation therapy:

"All tissues, normal and neoplastic, are affected by radiation so that radiosensitivity is a relative term. The basic consideration of radiation therapy is that cells that are actively proliferating or that cells which are of a primitive type are more sensitive than normal tissue so that there is usually a considerable margin between doses that are damaging to neoplastic and to normal cells. If this is the case, then a multifraction dose schedule decreases the size of the tumor over time while permitting time between doses for normal tissue to recover. A constant fraction of tumor cells are killed with each treatment, and theoretically the tumor can be completely eliminated with a sufficient number of treatments. **However, normal tissue has a memory of its accumulated radiation dose such that a threshold to the total dose acquired over the patient's history is eventually reached. Exceeding this threshold results in unacceptable side effects. Thus, the tumor volume must be reduced sufficiently before the threshold is reached or the cancer is incurable by this modality of therapy.**" Emphasis added.

Indeed, Mills teaches a therapy that relies upon Mossbauer absorption as an alternative to radiation with x-rays. See, also, Mills at, e.g., column 2, lines 4-17 ("In Mossbauer absorption, the source comprises excited nuclei in appropriate highly bonding surroundings. The nuclei, in decaying to their ground state, emit gamma radiation that is highly monochromatic."). Since Mills teaches the use of Mossbauer absorption with emission of gamma radiation for the therapy described therein, and teaches away from the use of irradiation with x-rays, there would have been no rationale or reason to modify Mills with Wang, as proposed by the Examiner, to arrive at the claimed invention. See MPEP 2143.01 ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.").

In view of the above, Applicant respectfully submits that the prior art and other rejections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,

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